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Office of Pesticide Programs  
(OPP) Regulatory Public Docket (7502P)  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW.  
Washington, DC 20460-0001

**DOCKET: EPA-HQ-OPP-2009-0635**  
(75 FR 68215 et seq., Dec. 23, 2009)

Dear Mr. Leifer:

On behalf of the Science & Environmental Health Network, a non-profit corporation concerned with the environment and public health, I submit the following comments on the U.S. Environmental Protection Agency's advance notice of proposed rulemaking setting forth several proposals for public disclosure of inert ingredient information (Docket ID # EPA-HQ-OPP-2009-0635).

We first congratulate EPA on instituting this long-overdue rulemaking process in response to the August 2006 petitions from 15 Attorneys General and the 22 NGO's. The advance notice of proposed rulemaking represents a serious initiative to contend with the problem of pesticide inert ingredients. We appreciate the opportunity to provide these comments.

We support public disclosure of as much information as possible about inert ingredients. We support EPA's proposal to mandate public disclosure on pesticide labels for hazardous inert ingredients. EPA should also mandate public disclosure of information for inert ingredients not shown to be hazardous to the extent registrants do not demonstrate it to be entitled to confidential treatment, on pesticide labels if possible.

We also support EPA's proposal to develop a more comprehensive rule to mandate public disclosure relating to all inert ingredients. This latter proposal is the main subject of these comments.

I. EPA Has Legal Authority Under FIFRA To Require Public Disclosure For All Inert Ingredients

“Inert ingredients” of pesticides are defined by FIFRA as any pesticide ingredient other than an “active” ingredient, regardless of whether the “inert ingredient” is in reality chemically or biologically inert.<sup>1</sup> EPA has concluded that consumers and users of pesticides should have broad access to information relating to all or most inert ingredients because that information would help them make informed choices.<sup>2</sup> We agree. Information relating to all pesticide inert ingredients should be made publicly available, on pesticide labels wherever possible. As we explain in this section, EPA has the authority under FIFRA to mandate public disclosure for all inert ingredients.

In the advance notice of proposed rulemaking, one of EPA’s proposals is to require public disclosure for hazardous inert ingredients that appear on several specified lists of hazardous chemicals. EPA has in the past determined that specific inert ingredients are hazardous and must be listed on pesticide labels, even if that information would otherwise be confidential. EPA has promulgated regulations providing that “[t]he Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.”<sup>3</sup> EPA has also identified specific “inerts of toxicological concern” required to be listed on pesticide labels.<sup>4</sup>

As legal authority for these requirements, EPA has relied on “the Administrator’s basic obligation under [FIFRA] of determining the risks which may be posed by a pesticide and imposing the necessary regulatory requirement to adequately control an unreasonable risk.”<sup>5</sup> These policies have been “designed to reduce the potential for adverse effects from the use of pesticide products containing toxic inert ingredients.”<sup>6</sup>

EPA has proposed to rely on this same authority for its new proposal for disclosure for hazardous inert ingredients. We agree that FIFRA’s labeling, misbranding and registration provisions provide EPA the authority to require labels to include information about all inert ingredients that may be hazardous. To accomplish the goals of those provisions, the information included on labels should permit full evaluation of the safety of each such inert ingredient, which means that it should not just identify the ingredient but should specify preferably the percentage amount of the ingredient in the pesticide, the

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<sup>1</sup> FIFRA section 2(m).

<sup>2</sup> 74 FR 68220.

<sup>3</sup> 74 FR 68217 (quoting 40 CFR 156.10(g)(7)).

<sup>4</sup> See 74 FR 68217 discussing 52 FR 13305 (April 22, 1987).

<sup>5</sup> 74 FR 68217 (quoting 40 FR 28252 (July 3, 1975) promulgating 40 CFR 162.10(g)(7)).

<sup>6</sup> 74 FR 68217 (quoting 52 FR 13305 (April 22, 1987) announcing identities of “inerts of toxicological concern.”)

approximate percentage or at the very least the rank order of ingredients by concentration.

EPA appears to believe, however, that the labeling, misbranding and registration provisions of FIFRA do not authorize EPA to require labels to disclose information for all inert ingredients, including those that are not determined to be hazardous.<sup>7</sup> In *NCAP v. Leavitt* (D.D.C., Mem. Op., Oct. 12, 2004), the district court held that FIFRA did not require that inert ingredient information be categorically required on labels. That case may not have fully tested whether FIFRA authorizes EPA to require label disclosure for all inert ingredients should EPA determine such listing to be appropriate. EPA should require labels to include information about all inert ingredients to the extent the labeling, misbranding and registration provisions of FIFRA provide EPA with discretion to do so.

Nevertheless, EPA is seeking to establish other sources of authority under FIFRA to require public disclosure for all inert ingredients, which would include those not determined specifically to be hazardous. The information disclosure provisions of FIFRA section 10 provide such an independent source of authority. That section provides that broad health and safety ingredient information “shall be made available for disclosure to the public,” as long as it is not subject to the confidentiality protections of that section.<sup>8</sup> According to EPA, public disclosure for all inert ingredients could be required if inert ingredients as a class are not entitled to confidential treatment under FIFRA section 10(b).<sup>9</sup> We agree.

There are two possible bases for determining that no inert ingredient information is entitled to confidential treatment under FIFRA section 10(b). Under one of these, as EPA has proposed, EPA would determine that the ability of competitors or others to reverse engineer pesticides without undue cost renders information for inert ingredients ineligible for confidential treatment.<sup>10</sup> We understand EPA to be considering a broad, programmatic determination that would apply to inert ingredients generally. We support this initiative and believe EPA may be able to determine that substantial information about inert ingredients, as a class of information, should not be entitled to confidential treatment. In the 1996 case *NCAP v. Browner*, the court found that even at that time there was “no genuine issue of material fact as to the economic feasibility of identifying the common names and CAS numbers of inert ingredients through ‘reverse engineering.’”<sup>11</sup>

FIFRA section 10(d)(1) provides a second basis for EPA to determine that no information for inert ingredients is entitled to confidential treatment. We urge EPA to assert this basis as well. FIFRA section 10(b) provides that EPA shall not make public trade secret or

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<sup>7</sup> 74 FR 68220, 68222.

<sup>8</sup> FIFRA section 10(d).

<sup>9</sup> 74 FR 68220, 68222.

<sup>10</sup> 74 FR 68220.

<sup>11</sup> *NCAP v. Browner*, 941 F. Supp. 197, 202 (D.D.C. 1996).

commercial information, that requirement is expressly made “subject to the limitations” in section 10(d).<sup>12</sup> Section 10(d)(1) broadly authorizes the public disclosure of a wide variety of information, whether it is otherwise confidential or not, relating to the effects on human health and the environment of all pesticide ingredients, including active and inert ingredients, impurities and degradation products.

Section 10 contains one exception relating specifically to inert ingredient information. Section 10(d)(1)(C) does not authorize the public disclosure of:

“the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to human health or the environment.”<sup>13</sup>

This is a narrowly-defined, qualified exception to the broad public disclosure required by section 10(d)(1). It does not preclude public disclosure of any information other than “identity or percentage quantity” information. Nor does it preclude public disclosure for pesticide ingredients other than those that are “deliberately added inert ingredients,” such as impurities and degradation products that are not “deliberately added.”

Thus, FIFRA section 10(d)(1)(C) authorizes EPA to publicly disclose information relating to all inert ingredients if it makes the required “unreasonable risk” determination. Nothing whatsoever in section 10(d)(1)(C) requires EPA to make this “unreasonable risk” determination solely on an ingredient-by-ingredient basis. Indeed, as discussed above, other labeling, misbranding and registration provisions of FIFRA already authorize EPA to make ingredient-by-ingredient hazard determinations to justify public disclosure.

Rather, section 10(d)(1)(C) plainly authorizes EPA to make a broader, programmatic determination that would apply to all inert ingredients. EPA can determine that:

Public disclosure of information relating to all inert ingredients in pesticides “is necessary to protect against an unreasonable risk of injury to health or the environment.”

If EPA does make this determination, it will be authorized under section 10(d)(1) to publicly disclose information for all inert ingredients, whether hazardous or not. We believe public disclosure would be authorized for pesticide inert ingredient identity and preferably the percentage amount of each such ingredient in the pesticide, the approximate percentage or at the very least the rank order of ingredients by concentration.

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<sup>12</sup> FIFRA section 10(b).

<sup>13</sup> FIFRA section 10(d)(1)(C).

The most effective form of public disclosure would be to include this information in pesticide labels. But, even if EPA concludes that under *NCAP v. Leavitt* FIFRA does not permit inert ingredients to be categorically listed on labels unless they are first determined to be hazardous (which we do not agree is a necessary interpretation of the case, as discussed above), other forms of public disclosure for all inert ingredients under FIFRA section 10(d)(1) are still permissible and reasonable. Public disclosure under FIFRA section 10(d)(1) is not the same as label disclosure, the subject of *NCAP v. Leavitt*. Under section 10(d)(1), information is to be made “available for disclosure to the public,” which can plainly be accomplished by a variety of means other than inclusion in labels including, for example, publication on the internet.

Section 10(d)(1) provides broader means of public disclosure options than just labeling because it serves different purposes than FIFRA’s labeling and misbranding provisions. Not all information that should be publicly disclosed is required to be included in labels, even if that is usually the most effective form of disclosure. The difference between labeling and section 10(d)(1) public disclosure is commonly recognized already. For example, otherwise-confidential health and safety studies may be made publicly available under section 10(d)(1), but that does not mean that those studies must also be included on pesticide labels. A similar result should govern information relating to inert ingredients not determined to be hazardous. It should be “made available for disclosure to the public” under section 10(d)(1) quite apart from whether EPA can or chooses to require it to be included in pesticide labels.

Our remaining comments focus on the basis for concluding that public disclosure for all inert ingredients is necessary to protect against an unreasonable risk of injury to human health or the environment under FIFRA section 10(d)(1)(C). EPA can make this determination based on two findings discussed in detail in the following sections. The first finding (discussed in Section II) is that the problem of environmental degradation is rooted in excessive cumulative impacts, including impacts by pesticides and pesticide inert ingredients, which makes any and all avoidable use of potentially hazardous inert ingredients “unreasonable.” The second finding (discussed in Section III) is that while public disclosure for hazardous inert ingredients will protect public health and the environment from known hazards, public disclosure for all inert ingredients would best minimize environmental impacts from inert ingredients. Based on these findings, EPA can and should conclude that public disclosure for all inert ingredients is “necessary to protect against an unreasonable risk of injury to human health or the environment” under FIFRA section 10(d)(1)(C).

## II. Because of the Rise of Cumulative Environmental Impacts, All Risks of Injury To Human Health And The Environment Should Be Avoided Wherever Possible

We urge EPA to determine that public disclosure of information about all inert ingredients is “necessary to protect against an unreasonable risk of injury to human health or the environment” under FIFRA section 10(d)(1)(C).

To make this determination, an essential question is: what is an “unreasonable risk” of injury to human health or the environment? FIFRA section 10(d)(1)(C) uses the term “an unreasonable risk of injury,” but FIFRA does not define that term. Similarly, FIFRA’s section 3 registration provisions authorize EPA to take various actions to prevent “unreasonable adverse effects on the environment,” which section 2(bb) defines as including “any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide.”<sup>14</sup> This “definition” provides a list of factors to consider in determining what risks are “unreasonable,” but it does not define what makes a risk “unreasonable.”

Historically, United States regulatory authorities have frequently determined whether chemical exposures are “reasonable” under federal environmental laws including TSCA and FIFRA by using chemical-by-chemical risk assessments and analyses of the costs and benefits of regulating exposures. A regulatory cost typically is deemed reasonable if the benefits of reducing a chemical exposure outweigh the costs as estimated by such a cost-benefit analysis. This is the approach generally taken by Executive Order 12,866, under which this advance notice of proposed rulemaking was reviewed.<sup>15</sup>

The Obama Administration is in the process of reviewing Executive Order 12,866. We have filed extensive comments on behalf of 24 co-signers with the Obama Administration in connection with this review, in which we argued in detail that it is no longer appropriate to evaluate each incremental environmental impact on a cost-benefit basis.<sup>16</sup> This decision-making method evaluates the costs and benefits of each particular environmental impact as though it alone were the only environmental hazard. Since all impacts are permitted to continue unless they are calculated to be “unreasonable,” this system therefore intentionally permits, as the economy grows forever, the unlimited growth of cost-benefit justified increments of environmental damage. There is no mechanism built into the cost-benefit decision-making structure that can restrain the cumulative costs of numerous incremental impacts.<sup>17</sup>

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<sup>14</sup> FIFRA, section 2(bb).

<sup>15</sup> See 74 FR 68223, discussing review of ANPR under Executive Order 12,866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993).

<sup>16</sup> Joseph H. Guth, Comments filed with Office of Management and Budget with 24 co-signers; “Re. New Executive Order on Regulatory Review,” March 16, 2009, available as comment no. 111 at: <http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp>. For additional discussion of how the rise of cumulative impacts has rendered cost-benefit environmental decision-making inappropriate, see Guth, J., “Cumulative Impacts: Death-Knell For Cost-Benefit Analysis in Environmental Decisions,” *Barry Law Review*, Vol.11, pp. 23-57, (Fall 2008 issue, published in July 2009), available at: [www.sehn.org](http://www.sehn.org).

<sup>17</sup> For further discussion of how cost-benefit decision-making allows indefinite growth of cumulative impacts and the underlying assumption of the possibility of endless growth in environmental degradation, see Guth, “Comments filed with Office of Management and Budget,” *supra*, at pp. 4-11. See also Guth, “Cumulative Impacts,” *supra*.

The central problem with this definition of “unreasonable risk” is that it ignores the critical and inescapable fact that there is a limit to the earth’s ability to tolerate environmental damage without jeopardizing the ecological systems human beings depend on to live. And there is no doubt that the growing cumulative impact of diverse environmental harms is now exceeding that limit.

Pesticides and inert ingredients are contributing factors in the widespread ecological degradation that is occurring today. Billions of pounds of pesticides are disseminated into the lands and waters of the United States every year. Numerous active ingredients are widespread in the bodily tissues of Americans, including certain fungicides, herbicides, carbamate insecticides, organochlorine pesticides, organophosphorus pesticides, and pyrethroid pesticides.<sup>18</sup> Often between 50% and 99% of the formulations of these pesticides are comprised of inert ingredients, many of which are also virtually certain to be contaminating human tissues and the environment.

Pesticide active ingredients, which are intended to be toxic and often to kill living organisms, are capable of causing a wide variety of adverse impacts on human health and the environment, including carcinogenicity, adverse reproductive effects, neurotoxicity and other chronic effects, developmental toxicity and ecological effects as well as persistence and the potential for bioaccumulation.<sup>19</sup> These effects can be caused by very low doses and after long latency periods. Moreover, multiple pesticide ingredients have been demonstrated to cause synergistic effects that are greater than the impact expected if the effects of the individual ingredients were additive. In one recent report, mixtures of five commonly used pesticides in California frequently produced synergistic inhibition of acetylcholinesterase at environmentally relevant doses in juvenile coho salmon.<sup>20</sup>

Inert ingredients are also capable of causing virtually the same wide variety of adverse effects.<sup>21</sup> Many hundreds of industrial chemicals that are used as inert ingredients are found on various government lists of hazardous chemicals.<sup>22</sup> Inert ingredients can enhance the toxicity of pesticides to the nervous, cardiovascular and hormone systems;

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<sup>18</sup> “Fourth National Report on Human Exposure to Environmental Chemicals,” at pp. 40-175, Center for Disease Control and Prevention, Department of Health and Human Services (2009) (available at: <http://www.cdc.gov/exposurereport/>).

<sup>19</sup> *Id.* (identifying numerous potential adverse effects on human health and the environment of dozens of particular active ingredients in fungicides, herbicides, carbamate insecticides, organochlorine pesticides, organophosphorus pesticides, and pyrethroid pesticides).

<sup>20</sup> Weinhold, “Synergy for Salmon: Study Spawns Insight Into Pesticide Mixtures,” *Environmental Health Perspectives*, Vol. 117, p. A117 (2009).

<sup>21</sup> See 74 FR 68217 (identifying adverse effects of “List 1” inert ingredients that EPA required to be listed on pesticide labels in 1987).

<sup>22</sup> See 74 FR 68218 (compiling from 2006 NGO petition lists of hazardous chemicals that include pesticide inert ingredients); Bob Weinhold, “Mystery in a Bottle: Will the EPA Require Public Disclosure of Inert Pesticide Ingredients?,” *Environmental Health Perspectives*, vol. 118, pp. 168-171 (April 1, 2010) (hundreds of inert ingredients are on lists of hazardous chemicals).

can increase the persistence and movement of pesticides in the environment; and can enhance the toxic effects of pesticides on non-target plants, animals and microorganisms in the environment.<sup>23</sup>

EPA has identified about 50% of the 3,000 to 4,000 thousand inert ingredients in use as having some hazard property that makes them at least moderately risky.<sup>24</sup> But these known hazards are very likely to be just the tip of the iceberg. EPA has identified the lack of information available to users and consumers about inert ingredients as a problem.<sup>25</sup> We agree that there is a profound lack of public information about the hazardous properties inert ingredients. When pesticides are registered with the EPA, some toxicity tests are required. But most of these tests are performed only on the active ingredients. Only one third to one half of the required tests for human health effects, and even fewer for effects on wildlife, must be performed on the pesticide formulations (which would include the inert ingredients).<sup>26</sup> This means that many potential long-term effects of the combinations of active and inert ingredients used in pesticide products are never assessed under FIFRA, including tests for cancer, reproductive harm and genetic damage.<sup>27</sup>

Many inert ingredients are industrial chemicals that may also be subject to other environmental laws, including the Toxic Substances Control Act. But the failure of TSCA to require the development of information about the toxicity of industrial chemicals is well documented.<sup>28</sup> A recent report examining the toxicity information

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<sup>23</sup> Caroline Cox and Michael Sorgan, “Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health,” *Environmental Health Perspectives*, vol. 114, pp. 1803-1806 (2006).

<sup>24</sup> *Id.* at p. 1804 (discussing and citing The Office of Pesticide Program’s Guidance Document on Methodology for Determining the Data Needed and the Types of Assessments necessary to make FFDCA Section 408 Safety Determinations for Lower Toxicity Pesticide Chemicals (available at: [http://www.epa.gov/oppfead1/cb/csb\\_page/updates/lowertox.pdf](http://www.epa.gov/oppfead1/cb/csb_page/updates/lowertox.pdf)).

<sup>25</sup> 74 FR 68218.

<sup>26</sup> Cox and Sorgan, “Unidentified Inert Ingredients in Pesticides,” *supra*, at p. 1804.

<sup>27</sup> *Id.*

<sup>28</sup> U.S. General Accounting Office, *Chemical Regulation—Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program* (GAO-05-458) (Washington, D.C. 2005); Guth, J., Denison, R., Sass, J., “Require Comprehensive Safety Data for all Chemicals,” Updated Background Paper for Reform No. 5 of the Louisville Charter for Safer Chemicals, *New Solutions: A Journal of Environmental and Occupational Health Policy*, Volume 17, Number 3, pp. 233-58 (2007), first published as “Require Comprehensive Safety Data For All Chemicals,” Background Paper for Reform No. 5 of the Louisville Charter for Safer Chemicals ([www.louisvillecharter.org](http://www.louisvillecharter.org))(2005); Wilson M., Chia D., Ehlers B., California Policy Research Center, University of California Office of the President, “Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation,” Special Report to the California Senate Environmental Quality Committee and the Assembly Committee on Environmental Safety and Toxic Materials (2006), available at: <http://coeh.berkeley.edu/greenchemistry>.



available from numerous public sources for nearly 10,000 industrial chemicals used in commerce, including inert pesticide ingredients, confirms the continued persistent and pervasive nature of the “data gap.”<sup>29</sup> The authors concluded that no information at all is available for one third of the 10,000 chemicals and detailed toxicology information (on a selected set of endpoints) is available for only one quarter of them.<sup>30</sup> And this does not even begin to reflect our lack of understanding of the cumulative and synergistic effects of pesticide ingredients as mixtures comprising other chemicals and environmental agents, which is after all what humans and the environment are exposed to in the real world.

These data gaps are especially troubling because it is becoming very clear that many or even most industrial chemicals are likely to be hazardous. The European Commission, in developing a proposal for the European Union’s REACH regulation, concluded in 2003 that 70% of the chemicals evaluated under its new chemicals program since 1981 were shown to have one or more dangerous properties. While it is difficult to estimate precisely what proportion of chemicals on the market are likely to be hazardous, it is also difficult to dispute the European Commission’s conclusion that under regulatory systems prevailing before REACH, a “significant proportion of all chemicals will enter the environment and reach sufficiently high concentrations to induce adverse effects.”<sup>31</sup> When it comes to inert pesticide ingredients, the most plausible starting assumption under today’s understanding of the effects of chemicals on the environment must be that, if they were thoroughly studied, most would be likely to be found inherently hazardous.

But there is a larger context for evaluating the risks of inert ingredients. Pesticides contribute to the cumulative impact on the environment of myriad destructive human activities. This cumulative impact is the root-cause of the mounting ecological degradation that is being widely and comprehensively reported by the world’s scientists.

Consider the example of the study cited above on the effects of pesticides on juvenile coho salmon.<sup>32</sup> We noted above that multiple pesticides used in the Pacific Northwest caused synergistic inhibition of acetylcholinesterase in salmon. But the larger context is that pesticide pollution of waterways is one contributing factor in the long-term habitat degradation that has brought the wild salmon populations Western United States to the brink of extinction.<sup>33</sup> While numerous factors are implicated in this decline in addition to

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<sup>29</sup> Judson et al., “The Toxicity Data Landscape for Environmental Chemicals,” *Environmental Health Perspectives*, vol. 117, pp. 685-95 (2009).

<sup>30</sup> *Id.* at pp. 693-94.

<sup>31</sup> European Commission, *Extended Impact Assessment* (SEC(2003)1171/3) (2003), available at: [http://ec.europa.eu/enterprise/reach/docs/reach/eia-sec-2003\\_1171.pdf](http://ec.europa.eu/enterprise/reach/docs/reach/eia-sec-2003_1171.pdf).

<sup>32</sup> Weinhold, “Synergy for Salmon,” *supra*.

<sup>33</sup> See S.T. Lindley et al., “What Caused the Sacramento River Fall Chinook Stock Collapse,” April 2009 Workgroup Report Pacific Fishery Management Council, (available at: [http://www.pcouncil.org/wp-content/uploads/H2b\\_WGR\\_0409.pdf](http://www.pcouncil.org/wp-content/uploads/H2b_WGR_0409.pdf)), at p. 15 (describing numerous factors in salmon fisheries decline and National Marine Fisheries Service opinion that

pesticides, it is also true that none of these factors by themselves would decimate the fishery. The fishery has nearly been destroyed by cumulative effect of numerous factors, a death by a thousand cuts, none of which taken alone would be fatal. And pesticide ingredients are one of those cuts.

Pesticides are similarly contributing to cumulative environmental impacts causing numerous ecological and human health problems all around the U.S. and the world. In 2005, the Millennium Assessment, a comprehensive assessment of the global environment compiled by over 2,000 scientists from 95 countries concluded that 60 percent of global ecosystem services are “being degraded or used unsustainably,” including fresh water supplies, capture fisheries, air purification, water purification, and the regulation of natural hazards and pests.<sup>34</sup> Excessive use of pesticides was reported to be contributing to this ecological damage, degrading the capacity of ecosystems to provide pest control in many agricultural areas.<sup>35</sup> Pesticides were reported to be putting humans at risk of adverse health effects, including endocrine disruption and acute health impacts.<sup>36</sup> The Millennium Assessment recommended reducing the use of pesticides through adoption of new government policies, development of economic incentives and creation of new technologies.<sup>37</sup>

In 2007, the United Nations Environment Programme published a report on current trends in environmental degradation.<sup>38</sup> It identified many elements of the environment that are being degraded<sup>39</sup> and concluded that we are now crossing thresholds of sudden,

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re-registration of three pesticides would jeopardize continued existence of 27 species of Pacific salmonids); “Chapter 3: Factors Leading to Federal Listing,” p. 49, in *Recovery Plan for the Evolutionarily Significant Unit of Central California Coast COHO Salmon*, March 2010 Public Draft, National Marine Fisheries Service (available at: [http://swr.nmfs.noaa.gov/recovery/Coho\\_Recovery\\_Plan\\_031810.htm](http://swr.nmfs.noaa.gov/recovery/Coho_Recovery_Plan_031810.htm)) (identifying pollution from agricultural pesticides as one of numerous factors contributing to habitat degradation).

<sup>34</sup> *Millennium Ecosystem Assessment, Ecosystems and Human Well-Being: Synthesis 2* (2005) [hereinafter Millennium Assessment], available at <http://www.millenniumassessment.org/documents/document.356.aspx.pdf>. The Millennium Ecosystem Assessment Reports together constitute an evaluation of the world’s ecosystems and human well-being that was carried out between 2001 and 2005 under the auspices of the United Nations. *Id.* at ii–ix. The reports are available at <http://www.millenniumassessment.org/en/index.aspx>.

<sup>35</sup> Millennium Assessment, *supra*, at pp. 43, 47.

<sup>36</sup> *Millennium Ecosystem Assessment Health Synthesis Report*, at p. 21. This is one of the Millennium Ecosystem Assessment Reports, and is available at: <http://www.millenniumassessment.org/en/index.aspx>.

<sup>37</sup> Millennium Assessment, *supra*, at pp. 21, 22, 95, 97.

<sup>38</sup> U.N. Env’t Program, *Global Environment Outlook—Environment for Development Geo-4*, at p. 6 (2007), available at [http://www.unep.org/geo/geo4/report/01\\_Environment\\_for\\_Development.pdf](http://www.unep.org/geo/geo4/report/01_Environment_for_Development.pdf) (this report was prepared by over 400 scientists and environmental policy makers).

<sup>39</sup> *Id.* at p. 202 (box 6.1).

irreversible environmental changes. Among other environmental impacts, this report documented widespread contamination of many regions of the earth's soils oceans and fresh waters by persistent toxic pesticides.<sup>40</sup> It concluded that long-term exposure to pesticides can increase the risk of developmental and reproductive disorders, disruption of the immune and endocrine systems, and can impair the function of the nervous system, is associated with the development of certain cancers and poses elevated risks to children.<sup>41</sup> The report recommended reduction in the use of pesticides<sup>42</sup> and the development of safer pesticides.<sup>43</sup>

In a similar vein, long-time leading American environmentalist James Gustave Speth recently concluded that despite current U.S. and global environmental laws, "We are losing the planet."<sup>44</sup> Speth identified growing pollution by toxic chemicals, including 6 billion pounds of pesticides per year in the U.S., as contributing to environmental degradation in the U.S.<sup>45</sup>

There is today widespread agreement that international and U.S. legal systems are not containing the mounting cumulative human impacts on the environment. For the first time in human history we are approaching and have likely surpassed the biosphere's assimilative limits. The World Wildlife Fund and its collaborators have found that, by the 1980's, humanity's "Global Ecological Footprint" had reached the capacity of the biosphere to provide resources and absorb waste; that by 2003 it had overshot that capacity by 25 percent; and that it continues to grow every year.<sup>46</sup> They concluded that humanity is now depleting reserves of ecological assets that accumulated on the Earth over long periods of time, and that we cannot do so much longer without damaging the Earth's ability to renew them.<sup>47</sup> Other groups of scientists have similarly concluded that in the last several decades, humanity's demands on the biosphere surpassed sustainable levels.<sup>48</sup>

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<sup>40</sup> *Id.* at pp. 94, 131, 135, 222, 238, 321.

<sup>41</sup> *Id.* at p. 321.

<sup>42</sup> *Id.* at p. 213.

<sup>43</sup> *Id.* at p. 153.

<sup>44</sup> James G. Speth, *The Bridge at the Edge of the World—Capitalism, the Environment, and Crossing from Crisis to Sustainability*, at p. 78 (2008) (outlining current environmental problems in the United States).

<sup>45</sup> Speth, "The Bridge at the Edge of the World," *supra*, at pp. 54, 77.

<sup>46</sup> Ben Collen et al., "Living Planet Index," in *2010 and Beyond*, at pp. 1 (Fig. 2), 8–9 (Jonathon Loh ed., 2008), available at: [http://www.wwf.org.uk/filelibrary/pdf/2010\\_and\\_beyond.pdf](http://www.wwf.org.uk/filelibrary/pdf/2010_and_beyond.pdf).

<sup>47</sup> *Id.* at p. 9.

<sup>48</sup> E.g., *Global Environment Outlook—Environment for Development Geo-4*, *supra*, concluding that human activities now require 54 acres (22 hectares) per person globally, but Earth can provide only 39 acres (16 hectares) per person without suffering permanent degradation); Mathis Wackernagel et al., "Tracking The Ecological Overshoot Of The Human Economy," *Proceedings of the National Academy of Sciences*, Vol. 99, No. 14 at 9266-9271 (July 9, 2002), available at:

The Millennium Assessment summarized its scientists' current evaluation of the cumulative human impact on the ecological systems of the Earth in these stark but clear terms:

“Human activity is putting such strain on the natural functions of Earth that the ability of the planet’s ecosystems to sustain future generations can no longer be taken for granted.”<sup>49</sup>

These scientific bodies have concluded that the only solution to the environmental problems we face is to contain and reduce our cumulative environmental impacts.<sup>50</sup> It is in this context that the dissemination into the environment every year of billions of pounds of inert ingredients must be evaluated. Comprehensive scientific and government reports virtually always include pesticides as contributing factors in the cumulative human environmental footprint. Focused on responding to the problem of cumulative impacts, these reports consistently recommend a reduction in the use of hazardous pesticides and the development of policy tools to promote development of safer ones.<sup>51</sup>

Disparities in environmental impacts are an additional acute environmental problem in the U.S. In studying this problem, the state of California has drawn a clear connection between environmental justice disparities and cumulative impacts. Between 1999 and 2001 the California adopted three state laws requiring California Environmental Protection Agency (“Cal/EPA”) to address the problem of environmental justice.<sup>52</sup> Under

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[http://www.precaution.org/lib/tracking\\_overshoot\\_of\\_human\\_economy.020719.pdf](http://www.precaution.org/lib/tracking_overshoot_of_human_economy.020719.pdf) (human demand constituted 70% of the biosphere’s regenerative capacity in 1961 and 120% of that capacity in 1999). See also Global Footprint Network web site:

<http://www.footprintnetwork.org/en/index.php/GFN/>.

<sup>49</sup> See Board of the Millennium Ecosystem Assessment, "Living Beyond Our Means: Natural Assets and Human Well-being," *Millennium Ecosystem Assessment* at p. 5 (2005), available at <http://www.precaution.org/lib/livingbeyonourmeans.050315.pdf> (introducing what it calls the "bottom line" of the *Millennium Ecosystem Assessment*).

<sup>50</sup> See, e.g., Speth, *supra*, at pp. 85–86 (growing cumulative environmental threats with ever-larger environmental consequences cannot be controlled by current U.S. system for environmental protection); Millennium Assessment, *supra*, at p. 99 (recommending that environmental decision-making control cumulative effects); *Global Environment Outlook—Environment for Development Geo-4*, *supra*, at pp. 111, 467 (explaining that tipping points are reached when cumulative effects reach thresholds of unsustainable damage, and concluding that existing environmental institutions have been unable to keep up with increasing cumulative environmental degradation); *2010 and Beyond*, *supra*, at pp. 2–3, 14–15, 23, 24 (outlining many components of the human ecological footprint and the many steps that must be taken to reduce it).

<sup>51</sup> Millennium Assessment, *supra*, at pp. 21, 22, 95, 97; U.N. Env’t Program, *Global Environment Outlook—Environment for Development Geo-4*, *supra*, at pp. 213, 153.

<sup>52</sup> These bills have been incorporated into California law in Government Code, Section 65040.12 (Title 7, Division 1, Chapter 1.5, Article 4), and Public Resources Code, Sections 71110-71116 (Division 34, Part 3). See summary of these three laws in “Recommendations of the California

these laws, Cal/EPA must, among other things, conduct its programs, policies, and activities, and promote enforcement of all health and environmental statutes, so as to “ensure the fair treatment of people of all races, cultures and income levels.”<sup>53</sup> As Cal/EPA has worked to comply with this mandate, a central issue has become the disparate “cumulative impacts” experienced by different populations within the state.<sup>54</sup> One of the four strategies that Cal/EPA has defined in developing its Environmental Justice Action Plan is to develop guidance on assessing, preventing and reducing disparities in cumulative impacts.<sup>55</sup> Clearly, for some communities such as farm worker communities, pesticide exposures are a major contributing factor to environmental justice disparities.

In sum then, the critical ecological and environmental justice problems faced by the U.S. are caused at root by cumulative impacts, including from pesticides, that are exceeding the earth’s ability to tolerate damage. If this continues indefinitely, the only possible result is the eventual destruction of the earth’s ecological systems on which we depend. The implications for environmental decision-making are profound.

The central assumption underlying the use of cost-benefit environmental decision-making, that endless growth of increments of damage is possible, is no longer valid. As is typical of threshold effects, once total environmental damage exceeds the earth’s ecological limits, the total cost to humanity (the loss of the ecological systems we need to survive) far surpasses the total calculated cost of all the individual increments of damage. This means that it is no longer scientifically justifiable to determine the reasonableness of environmental impacts, including those caused by inert ingredient risks, to human health and the environment by attempting to evaluate the costs and benefits of each impact independently.<sup>56</sup>

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Environmental Protection Agency (Cal/EPA) Advisory Committee on Environmental Justice to the Cal/EPA Interagency Working Group on Environmental Justice, Final Report,” at p. 3–7 (Cal/EPA 2003), *available at* <http://www.calepa.ca.gov/EnvJustice/Documents/2003/FinalReport.pdf>.

<sup>53</sup> Intra-Agency Environmental Justice Strategy, at p. 2 (Cal/EPA 2004), *available at* <http://calepa.ca.gov/EnvJustice/Documents/2004/Strategy/Final.pdf> (summarizing legislative mandate).

<sup>54</sup> See “Recommendations,” *supra*, at pp. 13, 15, 16, 23–26, 28, 31. See “Office of Environmental Health Hazard Assessment and the California Integrated Waste Management Board Call for Applications to the Cumulative Impacts and Precautionary Approaches Work Group,” at 1 (Cal/EPA 2007), *available at* <http://oehha.ca.gov/pdf/CIPAWorkgroupSolicitation.pdf>.

<sup>55</sup> “Environmental Justice Action Plan,” at pp. 2, 4 (Cal/EPA 2004), <http://calepa.ca.gov/EnvJustice/ActionPlan/>.

<sup>56</sup> For further discussion of how surpassing earth’s limits renders cost-benefit decision-making scientifically invalid, see Guth, “Comments filed with Office of Management and Budget,” *supra*; Guth, “Cumulative Impacts,” *supra*.

Numerous legal analysts have suggested adoption of legal goals like that of maintaining ecological integrity. For example Ackerman and Heinzerling as well as McGarity et al. have called for alternative methods of decision-making, and recommend what they call a precautionary approach that focuses on avoidance of harm and places the burden of proof on industrial interests to show they are not causing undue harm.<sup>57</sup> Recent reports by the National Academy of Sciences have also stressed the problem of cumulative impacts and have begun to explore the implications for risk assessment.<sup>58</sup>

We need a new understanding of an “unreasonable” environmental impact that is based on the message from the scientific community about the full world that has come upon us: the growing cumulative impact of the human footprint is threatening the ecological integrity of the biosphere, which we need to survive and prosper. Environmental decision-makers should adopt as an overarching priority for implementing the nation’s environmental laws the imperative of restraining the cumulative impact of our environmental damage to an ecologically sustainable scale. Viewed in this way, the overarching goal of any environmental program, including one governing inert pesticide ingredients under FIFRA, must be to seek to eliminate all avoidable environmental impacts. It should seek permanently and in all cases to use fewer harmful pesticides and substitute safer alternatives. All impacts that can be avoided should be considered “unreasonable.”<sup>59</sup>

Accordingly, EPA’s goal should no longer be to make individual determinations of whether particular inert ingredients can pass a cost-benefit test. It should be to implement a program of continual improvement where each and every hazardous use of an inert ingredient can be examined and either reduced or replaced. Accordingly, EPA should conclude that under our current circumstances, any and all avoidable use of

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<sup>57</sup> E.g., Frank Ackerman and Lisa Heinzerling, *Priceless: On Knowing The Price Of Everything And The Value Of Nothing*, at pp. 223-29 (The New Press 2004); Thomas O. McGarity et. al., *Sophisticated Sabotage: The Intellectual Games Used to Subvert Responsible Regulation*, at pp. 218-22 (Environmental Law Institute 2004). See also Guth, “Law for the Ecological Age,” *supra* (calling for new environmental decision-making structures and discussing many other legal writers who have made similar calls for legal reform).

<sup>58</sup> See National Research Council, *Science and Decisions: Advancing Risk Assessment*, at pp. 93-126 (National Academies Press 2009) (background exposures to other xenobiotic and endogenous chemicals that may impact the dose response relationship should be considered in gauging the risks from a particular, individual chemical’s exposure); National Research Council, *Phthalates and Cumulative Risk Assessment: The Task Ahead*, at p. 9 (National Academies Press 2008) (cumulative risk assessments should be done on groups of chemicals with common adverse outcomes or that affect the same organ system (e.g. male reproductive system)).

<sup>59</sup> For further discussion of environmental decision-making under conditions of excessive cumulative impacts, see Guth, “Comments filed with Office of Management and Budget,” *supra*; Guth, “Cumulative Impacts,” *supra*; Guth, J., “Law for the Ecological Age,” *Vermont Journal of Environmental Law*, vol. 9, Issue 3, pp. 431-512 (Spring 2008) (<http://www.vjel.org/journal/pdf/VJEL10068.pdf>).

potentially hazardous inert ingredients is “unreasonable” within FIFRA section 10(d)(1)(C).

III. Under EPA’s Market-Driven Regulatory Approach,  
EPA Should Mandate Public Disclosure for All Inert Ingredients

EPA has proposed a market-based mandatory public disclosure requirement for all inert ingredients.<sup>60</sup> We support this proposal.

As we have indicated, we also support EPA’s proposal to require public disclosure for those inert ingredients determined to be potentially hazardous. This hazardous-only disclosure requirement, an important first step, would enlist market incentives to protect public health and the environment from the inert ingredients identified as hazardous by EPA.

However, these same market incentives should be applied to all inert ingredients, including those that EPA does not determine are hazardous. Applying market incentives to the entire universe of inert ingredients would be more effective at reducing risks to human health and the environment than applying them only to those inert ingredients EPA determines are hazardous. Market incentives can be extended into the entire domain of inert ingredients by applying a public disclosure requirement to all inert ingredients.

We will show in this section why application of public disclosure requirements to all inert ingredients would cause reductions in use of potentially hazardous inert ingredients that would not be achieved with a hazardous-only disclosure program. As we showed in the previous section, under our current conditions of excessive cumulative environmental impacts, all avoidable use of potentially toxic inert ingredients is “unreasonable.” Based on these two showings, EPA can find that public disclosure for all inert ingredients is “necessary to protect against an unreasonable risk of injury to human health or the environment” under FIFRA section 10(d)(1)(C). Because it is therefore “necessary” under section 10(d)(1)(C), public disclosure for all inert ingredients is authorized under that section as well.

In the remainder of this section, we explain why extending market incentives to all inert ingredients by mandatory public disclosure requirements would result in greater reductions of risk to human health and the environment.

A. EPA’s Proposed Information Disclosure  
Program Is A Well-Validated Regulatory  
Tool For Addressing Hazardous Chemicals

EPA’s advance notice of proposed rulemaking includes a “Problem Statement” that describes a pervasive market failure in the pesticide market resulting from lack of information available to consumers and users about the safety of inert ingredients in

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<sup>60</sup> 74 FR 68220.



pesticides, and describes how a government-mandated information disclosure program can correct this market failure.<sup>61</sup> EPA has specifically requested comments on the relationship of disclosure of inert ingredient information to the fair and efficient functioning of the market,<sup>62</sup> and this section provides our comments on that issue.

We congratulate EPA on developing this Problem Statement and articulating the role for EPA that it envisions in addressing environmental problems caused by market failures. EPA's theory, which we need not repeat here, is sound. Over the last several decades, the field of information economics has demonstrated the crucial role of information in the proper operation of a market economy, and the serious economic consequences of "imperfect information" and "information asymmetries."<sup>63</sup> Government regulatory information transparency systems have emerged in the last several decades as a common regulatory tool in many diverse fields including nutritional labeling, campaign finance disclosure and the Toxics Release Inventory under EPCRA section 313.<sup>64</sup>

In the case of industrial chemicals, it has been recognized at least since the early 1980's that lack of publicly-available information is the cause of market failures leading to inefficient allocation of the costs of toxic substances, and consequently to inefficient excessive production of many chemicals.<sup>65</sup> I along with several co-authors have recently discussed information economics and the importance of publicly-available information in enabling market demand for safer products to drive development of those products, and stressed that current data gaps are impeding that process in the chemicals market.<sup>66</sup> And

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<sup>61</sup> 74 FR 68218-219.

<sup>62</sup> 74 FR 68219.

<sup>63</sup> For overview of information economics, see J.E. Stiglitz, "Information and the Change in the Paradigm in Economics, Part 1," *The American Economist*, 47:6-26 (2003); J.E. Stiglitz, "Information and the Change in the Paradigm in Economics, Part 2," *The American Economist*, 48:17-49 (available at <http://www2.gsb.columbia.edu/faculty/jstiglitz/papers.cfm>) (2004); and J.E. Stiglitz. *Globalization and Its Discontents*, New York: W.W. Norton & Company, Inc.: 73-74, 261n.2. 2003.

<sup>64</sup> For a review of numerous transparency policies in diverse fields and study of attributes that make such policies effective, see Archon Fung, David Weil, Mary Graham and Elena Fagotto, "The Political Economy of Transparency: What makes disclosure policies effective," Ash Institute for Democratic Governance and Innovation, John F. Kennedy School of Government, Harvard University (2004), available at: <http://www.innovations.harvard.edu/showdoc.html?id=6784>.

<sup>65</sup> Jeffrey Trauberman, "Statutory Reform of 'Toxic Torts': Relieving Legal, Scientific and Economic Burdens on the Chemical Victim," 7 *Harv. Envtl. L. Rev.* 177, 184-87 (1983) (discussing chemicals market, the importance of the assumption of perfect information to efficiency, the lack of information in the chemicals market and consequent inefficiencies).

<sup>66</sup> Guth, J., Denison, R., Sass, J., "Require Comprehensive Safety Data for all Chemicals," Updated Background Paper for Reform No. 5 of the Louisville Charter for Safer Chemicals, *New Solutions: A Journal of Environmental and Occupational Health Policy*, Volume 17, Number 3, pp. 233-58 (2007), first published as "Require Comprehensive Safety Data For All Chemicals,"



Wilson et al. of the University of California at Berkeley in their recent groundbreaking report on Green Chemistry have discussed how data gaps in the chemicals market are impeding the development of green chemistry and recommended that those gaps be closed by provision of publicly available chemical information.<sup>67</sup>

EPA's Problem Statement sets forth a cogent case for use of an information transparency strategy to drive the market toward less use of hazardous inert ingredients and the development of safer alternatives. We agree with and support EPA's analysis and policy goals, but we recognize that it must be carefully designed if it is to accomplish these goals. Experience shows that transparency programs create a new set of incentives for market actors and must be carefully designed if they are to be effective in promoting intended policy goals while avoiding producing unintended consequences.<sup>68</sup> The users and consumers of inert ingredients have differing goals and motivations, and so it is critical to consider the incentives for each of them that would be created by EPA's proposed regulatory transparency program.<sup>69</sup>

As a preliminary issue, EPA has raised the question of whether the disclosure programs it proposes should be voluntary or mandatory.<sup>70</sup> We think the evidence is clear that there is virtually no possibility that a voluntary information disclosure program would work.<sup>71</sup> In the case of pesticides, only a mandatory disclosure program can produce the level playing field for all market participants that industry needs.

We believe it is clear that application of a public disclosure requirement to all inert ingredients, rather than to hazardous ones only, would be more effective in reducing risks to human health and the environment. In the subsections below, we outline our reasons for reaching this conclusion.

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Background Paper for Reform No. 5 of the Louisville Charter for Safer Chemicals ([\(www.louisvillecharter.org\)](http://www.louisvillecharter.org)(2005).

<sup>67</sup> Wilson M., Chia D., Ehlers B., California Policy Research Center, University of California Office of the President, "Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation," Special Report to the California Senate Environmental Quality Committee and the Assembly Committee on Environmental Safety and Toxic Materials at pp. 23, 41, 55 74 (2006), available at: <http://coeh.berkeley.edu/greenchemistry>.

<sup>68</sup> For a discussion of why some transparency programs are more effective than others at accomplishing policy goals and of unintended consequences, see Fung et al. "The Political Economy of Transparency," *supra*.

<sup>69</sup> *Id.*

<sup>70</sup> 74 FR 68222.

<sup>71</sup> For discussion of the importance of mandatory public disclosure to the effectiveness of transparency strategies, see Fung et al. "The Political Economy of Transparency," *supra*.

B. Requiring Disclosure For All Inert Ingredients Would Promote Reduced Use And Development Of Safer Alternatives For All Potentially Hazardous Inert Ingredients

Public disclosure for only those ingredients determined to be hazardous would divide the universe of inert ingredients into two classes: those that are publicly disclosed and those that are not.

As EPA has explained, consumers and users of pesticides who wish to avoid publicly disclosed hazardous inert ingredients would drive the market away from products containing them. Pesticide manufacturers and industrial users of pesticides would rationally have substantial motivation to avoid using disclosed inert ingredients and to use non-disclosed alternatives instead. Industry will respond to the market forces that will result when consumers and users of pesticides make their choices. Industry may also be exposed to adverse publicity, tort liability and regulatory action if it continues to use inert ingredients EPA determines to be hazardous. All of these motivating factors would ensure that the pesticide market would shift to inert ingredients whose public disclosure is not required. There is good evidence that this market shift would indeed happen in the pesticide market. EPA has reported that since it required labels to identify one set of about 50 hazardous inert ingredients, most of those ingredients have “disappeared” from pesticides.<sup>72</sup>

However, the incentives and disincentives would be far different for the non-disclosed inert ingredients. They would not be subject to market pressures influencing their use. They would not be subject to regulatory pressures. They would not be subject to liability concerns, adverse publicity or any other incentives. They would simply be hidden from the public and the market. They would remain entrenched in the market, protected by the regulatory system from any scrutiny at all. Thus, a permanent hazardous-ingredient only disclosure program, though desirable as an interim step, would create what can only be called a regulatory safe harbor for all non-disclosed inert ingredients.

Under a hazardous-only disclosure program, EPA must rely on an evidentiary test for concluding that an inert ingredient is “hazardous.” There will inevitably be some cases in which there is some evidence of hazard (such as early warnings of harm) that EPA will conclude is insufficient to meet that test. In such cases, those potentially hazardous ingredients would enjoy the same regulatory safe-harbor status as ingredients that are truly safe. For such potentially hazardous inert ingredients, the market would be disabled from responding to the evidence of harm and would be unable to promote reduction in use or development of safer alternatives. Those potentially hazardous inert ingredients would simply stay on the market, hidden from public or market scrutiny, their potential hazards unrecognized.

EPA’s goal should be to motivate a perpetual search to reduce use and develop safer alternatives for all potentially hazardous inert ingredients, not just those that EPA decides

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<sup>72</sup> 74 FR 68217.

meet its test for “hazardous.” EPA should not create a safe harbor for potentially hazardous inert ingredients with some evidence of harm but that fail to meet that test.

EPA’s hazard-only disclosure proposal would bring much-needed market incentives to bear on creating safer alternatives and reducing use of inert ingredients EPA determines are hazardous. Those same market incentives should be brought to bear on all inert ingredients. EPA should let the market decide, for all inert ingredients, which are safe enough to use and which should be replaced by safer alternatives.

C. A Safe Harbor for Non-Hazardous Inert Ingredients  
Would Create Incentives for Industry to Perpetuate Data Gaps

As we described in the previous section, public disclosure of only those ingredients determined to be hazardous would divide the universe of inert ingredients into two classes: those that would be publicly disclosed, and those that would not be. For the latter, a regulatory safe harbor would be created, and the market would shift towards their use.

Once industry switches to non-disclosed inert ingredients, it will be motivated to perpetuate the non-disclosed status of those ingredients. It will be motivated to resist providing any toxicity information about those ingredients that may prompt EPA to determine they are “hazardous” and lose their safe harbor status. In other words, incentives would be created for industry to perpetuate any data gaps that lie at the root of the safe harbor for their products.

In contrast, if public disclosure were required for all inert ingredients, data gaps would become a matter of public knowledge. The data gaps themselves are a problem that the market is capable of addressing, for consumers and users of inert ingredients can demand that the pesticide industry fill those gaps if they can be identified. Hence, public disclosure for all inert ingredients would help close rather than perpetuate data gaps.

Thus, while we support EPA’s proposal for a hazardous inert ingredient only disclosure program as an interim step, EPA s

ingredients are pervasive. This virtually assures that at least some inert ingredients not yet recognized as hazardous are in fact inherently hazardous. Indeed, it is very likely that at least some of the substitutions driven by a hazardous ingredient only disclosure program would turn out to be hazardous as well, and sometimes even worse for human health and the environment.

This problem of “regrettable substitutions” plagues virtually all piecemeal regulation of chemicals in the absence of a comprehensive program.<sup>73</sup> As just one example, it is likely that EPCRA’s section 313 Toxics Release Inventory disclosure program for a specified list of chemicals has led industry to reduce use of TRI chemicals by, in at least some cases, switching to non-listed chemicals that are nevertheless hazardous, and this has reduced the effectiveness of that program’s ability to achieve the policy goal of protecting public health.<sup>74</sup>

One might hope for a substantial toxicity information requirement for all inert ingredients. This would provide a much greater basis for confidence that substitutes for hazardous inert ingredients would not themselves be hazardous. But in the absence of such a requirement, which is the unfortunate reality we are faced with, the “disappearance” from pesticides of those inert ingredients EPA is able to determine are hazardous will not always represent a reduction in risk to human health and the environment.

The best and perhaps only way to minimize the occurrence of regrettable substitutions is to mandate public disclosure for all inert ingredients. This would give the market the best chance to replace hazardous inert ingredients with alternatives that are truly safer.

E. A Transparency Requirement For All Inert  
Ingredients Would Maximize The Efficiencies  
Offered By The Information Disclosure Program

Implementation of a requirement for public disclosure for all inert ingredients involves a single regulatory decision by EPA as to which inert ingredients the requirement would be applied to – all of them. At that point, one of the great benefits of regulatory transparency programs would be realized. It would enlist the power of the market, including literally thousands of concerned market participants, to make rapid and efficient decisions about how best to use pesticides and which inert ingredients were safest. An informed market could make more efficient and particularized decisions than could EPA regarding use of pesticides under diverse circumstances. And it could move far faster than EPA ever could to accommodate new information.

In contrast, a transparency program directed only at hazardous inert ingredients would require EPA to rely on a case-by-case determinations that particular inert ingredients present an unreasonable risk. The 2006 petitions do identify numerous classes of

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<sup>73</sup> Wilson et al., “Green Chemistry in California,” *supra*, at pp. 23, 41, 55 74.

<sup>74</sup> Fung et al., “The Political Economy of Transparency,” *supra*, at pp. 4, 25.

chemicals that EPA can reasonably conclude meet this standard, and these group classifications seem eminently reasonable. Nevertheless, case-by-case determinations would still have to be made for thousands more inert ingredients that would not be included on those lists.

This would put EPA in the position of making hazard determinations for thousands of inert ingredients, virtually in perpetuity. Many such decisions would be difficult. In reaching every such decision, EPA would be required to grapple with the difficulties of interpreting new and emerging scientific toxicity data, the particular uses of each pesticide involved and all the other controversial issues inherent in risk assessment and cost benefit analysis. Decisions would have to be revisited whenever significant new information emerged.

Moreover every decision to require public disclosure of one or more additional inert ingredients would require a new rulemaking. Every new rule could be challenged, either by industry or by public health advocates. Obtaining each final decision would be time consuming. Each decision would be subject to political influence in the then-current administration.

Thus, the process of EPA identification of new hazardous inert ingredients under a hazardous-only disclosure program would be much more cumbersome and much less particularized than the decisions the market would be capable of making if public disclosure for all inert ingredients were required.

While we support EPA implementing its hazardous inert ingredient disclosure proposal as an interim step, we do not believe that EPA should put itself permanently in the position of being the “decider.” If EPA permanently inserts itself as a gatekeeper into the process of deciding the inevitably controversial issues of which inert ingredients will be designated as hazardous and which will not, EPA would be giving up many of the main advantages of information disclosure regulatory strategies. A transparency program for all inert ingredients would clearly make best use of the power of the market and be far simpler, more efficient and more effective at reducing risks of inert ingredients than a more limited hazard-only disclosure program.

F. Disclosure For All Inert Ingredients Is Necessary To Foster A Market That Competes On The Basis Of Safety

EPA has expressed concern about potential negative effects on innovation in the pesticide market, and has asked for comments on that issue.<sup>75</sup>

We urge EPA not to fall prey to this misplaced concern.

There are many reasons industry rationally does not wish to reveal inert ingredient information for any ingredient that is known to be hazardous or which might be if it were

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<sup>75</sup> 74 FR 68219, 68221.

studied. These include subjecting their products to potential adverse market forces provided by consumers and users of their products, adverse publicity, tort liability and regulatory restrictions. These reasons, while very real, are difficult for any particular company to admit to, so that industry's most common objection to public disclosure requirements is alleged effects on innovation and competition.

Inert pesticide ingredients, like industrial chemicals generally, currently compete solely on the basis of price and function.<sup>76</sup> There is virtually no competition on the basis of safety and virtually no market incentive for innovation of safer products. That is precisely the market failure EPA has so cogently identified. The only way to create a market in which inert ingredients compete also on the basis of safety is to require safety

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more widespread within industry than in the public domain, and that industry objections to its disclosure have more to do with non-competitive reasons (exposure to market forces, publicity, tort liability and regulation) than with competition or free-riders.

Finally, even if innovation of new inert ingredients would suffer under a disclosure requirement, that innovation would relate to attributes of products other than safety – innovation on safety is not occurring precisely because of the market failure EPA has identified. EPA is authorized to determine, and should determine, that the benefits to society of promoting innovation of safer inert ingredients outweigh any other impacts that there may be on some forms of innovation.

To conclude this section then, a government mandated information disclosure requirement applied to all, rather than just hazardous, inert ingredients would be much more effective at protecting against risks of injury to human health and the environment from inert ingredients. The market incentives and disincentives that would be applied to all those inert ingredients not determined by EPA to be hazardous would result in reduced use of potentially hazardous inert ingredients, motivate the search for safer alternatives to them, motivate closing of data gaps, minimize the occurrence of regrettable substitutions, and better promote innovation of safer inert ingredients. While a hazardous-only disclosure requirement would be useful as an interim step to protect human health and the environment from known hazards, disclosure for all inert ingredients is preferable in the longer term.

As we showed in the previous section, under our current conditions of excessive cumulative environmental impacts, all avoidable use of potentially toxic inert ingredients is “unreasonable.” Therefore it follows that public disclosure for all inert ingredients is “necessary to protect against an unreasonable risk of injury to human health or the environment” under FIFRA section 10(d)(1)(C).

#### IV. Related Issues

We offer here a few very brief additional comments on some related issues.

Disclosure on labels. EPA has requested advice as to exactly what inert ingredient information should appear on pesticide labels and how it should be presented.<sup>80</sup> Information that is publicly disclosed under EPA’s hazardous inert ingredient disclosure proposal should be disclosed on labels. As for public disclosure relating to all inert ingredients that we advocate, we have not taken a detailed position on that issue herein. If it is consistent with the other provisions of FIFRA, identification of essentially all inert ingredients on labels would seem preferable and likely to minimize confusion as to exactly what ingredients are contained in particular pesticide products. Research as to the properties of each active and inactive ingredient would still have to be performed, but elimination of confusion as to product contents would be of substantial value. We do not

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<sup>80</sup> 74 FR 68221.

believe that label disclosure of all inert ingredients would be misleading, as EPA suggests,<sup>81</sup> as long as EPA is clear that labels are intended to identify all inert ingredients, whether hazardous or not. If that is not possible or practicable or there are countervailing concerns, some other way of making the information available to the public should be adopted. Accessible public disclosure would be useful to the market and to the many thousands of public health professionals, state agencies, industrial users of pesticides, environmentalists, academics, consumer advocates and sophisticated consumers who have the ability to make use of the information and promote decisions based on it.

Concentration information. EPA has requested comments on what inert ingredient information should be publicly disclosed.<sup>82</sup> The information for which disclosure requires an “unreasonable risk” determination under FIFRA section 10(d)(1)(C) is “the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.” We believe that all this information is preferable for the complete evaluation of the safety of pesticides and to realize the policy goals we have articulated herein. However, it may be possible to perform sufficient safety evaluations with concentrations specified in approximate terms or in terms of ranges rather than as precise concentrations. It may also be satisfactory to list inert ingredient information in order of concentration. The real test is what information is sufficient to provide the market with the information it needs to prevent unreasonable risks of injury to human health and the environment from inert ingredients.

De Minimus thresholds. EPA has requested comments on whether disclosure should be required for all inert ingredients, regardless of amount, or whether there should be a *de minimus* reporting threshold.<sup>83</sup> We believe there should be no threshold for any intentionally added inert ingredient, whether hazardous or not. In the context of the broad information disclosure for essentially all inert ingredients that we advocate, we do have some sympathy for a *de minimus* threshold for inert ingredients that arise as degradation products or impurities and are not determined to be hazardous. There may be large numbers of such contaminants present at very low concentrations that would be unduly burdensome to identify and disclose. We suggest that EPA develop some information on this point so that any potential burden on industry can be fairly evaluated.

CBI Claim Procedures. Finally, EPA has requested comments on the procedures for identifying confidential business information to the extent it is permitted.<sup>84</sup> We agree that EPA should not put itself in a position bearing extensive burdens to challenge overbroad industry CBI claims. If the CBI claim is important to a particular industry, it should be willing to establish entitlement to assert the claims, which serve to remove information that would otherwise be of benefit to the public. We recommend the following procedures for all CBI claims.

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<sup>81</sup> 74 FR 68221.

<sup>82</sup> 74 FR 68221.

<sup>83</sup> 74 FR 68220.

<sup>84</sup> 74 FR 68221.



1. A party seeking CBI designation for any inert ingredient information should assert each basis for such designation in writing when the information is submitted to EPA.
2. EPA should make a case-by-case determination as to whether the party has established that such designation is appropriate.
3. The submitting party should provide EPA with a redacted, public version of each filing in order to relieve EPA of the burden of preparing such documents. If EPA determines that some of the redacted information is not entitled to CBI protection, then the submitting party should provide EPA with a new public version of the filing.
4. Each grant of CBI protection should be time limited, subject to renewal and reevaluation by EPA upon application by the submitter.
5. The public should be notified of all CBI designations approved by EPA and provided sufficient information, including the basis for each such designation, to challenge that designation.

## V. Conclusion

EPA should require pesticide labels to include information about all hazardous inert ingredients. It should require disclosure, on labels if possible, for all inert ingredients not shown to be entitled to confidential treatment under FIFRA section 10. EPA should also develop a more comprehensive public disclosure program for all inert ingredients.

EPA has authority for the broader disclosure requirement. EPA should determine that information otherwise protected from disclosure under section 10(d)(1)(C) is not entitled to confidential treatment because it can be reverse engineered without undue cost. EPA should also determine that inert ingredient information otherwise protected from disclosure under FIFRA section 10(d)(1)(C) must be publicly disclosed to protect against an unreasonable risk of injury to human health or the environment. This latter determination is justified by the fact that ongoing environmental degradation is rooted in excessive cumulative impacts, including impacts by inert ingredients, making any and all avoidable use of potentially hazardous inert ingredients unreasonable. While public disclosure for hazardous inert ingredients will protect public health and the environment from known hazards, the environmental impacts from all inert ingredients are best minimized by public disclosure for all inert ingredients. Therefore, disclosure for all inert ingredients is “necessary to protect against unreasonable risks” under section 10(d)(1)(C).

Public disclosure for all inert ingredients authorized under Section 10(d)(1) should include ingredient identity as well as preferably the percentage amount of each such

ingredient in the pesticide, the approximate percentage or at the very least the rank order of ingredients by concentration. This information should be included on pesticide labels if possible, but it should be made available for disclosure to the public by some other means if EPA cannot or declines to require it to be included in labels under FIFRA's labeling, misbranding and registration provisions.

Thank you for the opportunity to submit these comments. We would be happy to answer any questions, provide additional material, and otherwise assist EPA in this important matter.

Very truly yours,

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